In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 6, 2023

DEE ANN QUANTIE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	No. 18-610V Special Master Gowen Ruling on Entitlement; Influenza Vaccine; Shoulder Injury Related to Vaccine Administration; ("SIRVA"); Table Injury.

Andrew D. Downing, Downing, Allison & Jorgenson, Phoenix, AZ, for petitioner.
Katherine C. Esposito, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On April 30, 2018, Dee Ann Quantie ("petitioner") file a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that she suffered a Shoulder Injury Related to Vaccine Administration ("SIRVA") as a result of receiving an Influenza ("flu") vaccination in her right shoulder on October 5, 2017. Petition (ECF No. 1).

After a review of the record as a whole including medical records, affidavits, pre-hearing briefing by the parties, an entitlement hearing, and for the reasons set forth below, I find by preponderant evidence that the petitioner is entitled to compensation.

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[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

I. Procedural History

Petitioner filed her petition on April 30, 2018, alleging that she sustained a right shoulder injury caused by the flu vaccine administered on October 5, 2017. Petition at Preamble. Petitioner filed an affidavit on April 30, 2018, and a supplemental affidavit on July 2, 2018, based on her own personal knowledge. Petitioner's Exhibit ("Pet. Ex.") 1 (ECF No. 1); Pet. Ex. 17 (ECF No. 12).

The case was initially referred to the Special Processing Unit ("SPU"). *See* SPU Initial Order (ECF No. 5). Respondent filed a status report on March 20, 2019, indicating his intention to continue to defend the case. (ECF No. 23). On May 6, 2019, respondent filed his Rule 4(c) Report, stating that compensation should be denied and the case dismissed for failure to demonstrate entitlement to compensation. Respondent's ("Resp.") Report ("Rept.") at 1 (ECF No. 24). Specifically, respondent stated that petitioner has not established a Table injury because petitioner demonstrated fat necrosis that was more likely the cause of her right shoulder injury. Resp. Rept. at 5-6. Additionally, respondent stated that petitioner's medical records do not demonstrate onset of a right shoulder injury within forty-eight hours of vaccine administration. *Id*. at 7.

On August 26, 2019, petitioner filed an expert report from Dr. Marko Bodor.[3] Pet. Ex. 20 (ECF No. 31). The case was reassigned to my docket on October 28, 2019. *See* Notice of Reassignment, October 28, 2019. On January 12, 2020, respondent filed an expert report from Dr. Geoffrey Abrams.[4] Resp. Ex. A (ECF No. 37). Petitioner filed a responsive expert report from Dr. Bodor on February 20, 2020. Pet. Ex. 27 (ECF No. 40). On May 1, 2020, respondent file a supplemental expert report from Dr. Abrams. Resp. Ex. C (ECF No. 44).

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[3] Dr. Marko Bodor is a Doctor of Physical Medicine and Rehabilitation, with sub-specialties in pain management and sports management. Pet. Ex. 33 (ECF No. 58). He received his undergraduate degree from Harvard College in 1982 and received his medical degree from the University of Cincinnati Medical School in 1987. *Id.* at 1. Dr. Bodor is licensed in the state of California, and he is board certified in neuromuscular and electrodiagnostic medicine. *Id.* at 1. He previously held positions as an emergency physician and attending physiatrist from 1988 through 1994. *Id.* Since 1995, he has practiced as an interventional physiatrist in private practice. *Id.* at 2. Additionally, Dr. Bodor serves a voluntary assistant professor at the Department of Neurological Surgery at the University of California San Francisco. *Id.* at 1. Dr. Bodor continues to treat approximately thirty patients per day. *Id.* at 2. Additionally, Dr. Bodor has written and co-authored numerous peer-reviewed medical articles, including the article, *Vaccination related shoulder dysfunction,* which the respondent cited when proposing to add SIRVA to the Vaccine Injury Table. Dr. Bodor was admitted as an expert in physical medicine and rehabilitation with a subspecialty in sports medicine. Tr. 109.

[4] Dr. Abrams currently serves as Assistant Professor of Orthopedic Surgery at the Stanford University School of Medicine. Resp. Ex. B at 1. He also holds the appointment of Staff Physician at the Veterans Administration Palo Alto Health Care Division. *Id.* Dr. Abrams is the Director of Sports Medicine for Stanford University Varsity Athletics as well as Director of the Lacob Family Sports Medicine Center at Stanford University. *Id.* He also serves as Team Physician for numerous professional and collegiate sports teams in the San Francisco Bay Area. *Id.*at 25. Dr. Abrams received his medical degree from the University of California San Diego. *Id*. at 1. He competed a surgical internship at Stanford University Hospital and Clinics from 2007 to 2008; and completed his residency in 2012 at the same hospital in the Department of Orthopedic Surgery. *Id.* at 1-2. Dr. Abrams also has a subspecialty certificate in Orthopedic Sports Medicine. *Id.* at 2. He has a surgical practice focused on orthopedic conditions of the shoulder and authored or co-authored over sixty peer-reviewed medical articles on various orthopedic topics. *Id*. at 2-24. Dr. Abrams was admitted as an expert in orthopedics and sports medicine. Tr. 201.

On August 26, 2020, I held a status conference, where I explained that petitioner has provided credible evidence to support the onset of pain within 48 hours of receiving the flu vaccination. *See* August 26, 2020, Scheduling Order (ECF No. 47). I ordered petitioner to submit a reasonable demand to respondent and for respondent to file a status report providing an update on settlement discussions. *Id*. at 3. On December 15, 2020, I held another status conference where the parties indicated that settlements discussions were unsuccessful. December 15, 2020, Scheduling Order, ECF No. 51. I directed the parties to submit a joint status report to schedule a two day entitlement hearing. *Id*. at 2.

An entitlement hearing was set for November 8, 2021-November 9, 2021. Hearing Order (ECF No. 53). Petitioner filed a pre-hearing brief on September 24, 2021. Pet. Pre-Hearing Brief (ECF No. 55). Respondent file a pre-hearing brief on October 25, 2021. Resp. Pre-Hearing Brief (ECF No. 56). A one day entitlement hearing was held on November 8, 2021. On November 16, 2021, I held a status conference and directed the parties to resolve the case informally. *See* November 16, 2021, Scheduling Order (ECF No. 66). I also directed the parties to file a joint status report on informal resolution and proposing post-hearing brief schedule. *Id*.

On December 17, 2021, the parties filed a joint status report indicating that respondent would not be settling the case and his intention to continue to defend the case. *See* December 17, 2021, Joint Status Report (ECF No. 68). Additionally, the parties indicated to the court that they did not believe post-hearing briefs were necessary for the case to proceed. *Id*.

This matter is now ripe for adjudication.

II. Evidence Submitted

a. Petitioner's medical history pre-vaccination

Petitioner is an Operations Supervisor for the Social Security Administration, and her responsibilities require that she is on the computer for the majority of her workday. Pet. Ex. 1 ¶ 2. Petitioner's pre-vaccination history was significant for a vitamin B12 deficiency for which she received monthly vitamin B12 shots beginning in August 2013. Pet. Ex. 2 at 5-6. Her B12 deficiency was a result of malabsorption from a prior gastric bypass surgery. *Id*. at 5-6. Petitioner filed medical records of monthly B12 shots from January to October 2017, of which seven were in her right arm. Pet. Ex. 18 at 23-33.

Prior to the vaccination at issue, Mrs. Quantie enjoyed playing outdoors, being with her grandchildren, participating in recreational target practice. Pet. Ex. 1 ¶ 3.

b. Petitioner's medical history post-vaccination

On October 5, 2017, petitioner was a 47-year-old woman, and received a flu vaccine in her right deltoid while visiting her primary care provider ("PCP"). Pet. Ex. 7 at 17. She was visiting the PCP for a scheduled visit regarding her anemia, and also received a B12 injection in her left deltoid. Pet. Ex. 16 at 1; Pet. Ex. 18 at 22. The following day, October 6, 2017, petitioner stated that had "pain" at the injection site and there was "redness surrounding the

injection site. Pet. Ex. 1 ¶ 5-6. Petitioner stated that she showed her "red and swollen arm" to her daughter Kaylee. Pet. Ex. 17 at ¶ 1. She stated that when she returned to work on Monday, October 9, 2017, petitioner showed her arm to four of her coworkers. *Id*.

Petitioner had an appointment with her PCP on October 19, 2017. Pet. Ex. 2 at 5. Under "Reason for Appointment," the record from this date stated, "1. Anemia." *Id.* The record from this date assessed petitioner with, "1. Iron deficiency anemia, unspecified iron deficiency anemia type-D50.9 (Primary); 2. Deficiency of vitamin B12-E53.8." *Id.* Further, the record also shows petitioner's bloodwork results. *Id.* The musculoskeletal exam stated "normal, no swelling or deformity." Pet. Ex. 2 at 5. In her affidavit, petitioner explained that this appointment was made at the doctor's request to "discuss some abnormal blood test results, and at that time, I was more concerned about my anemic condition and not focused on my shoulder condition." Pet. Ex. 17 at ¶ 3.

On October 22, 2017, petitioner had an appointment at Access Urgent Care. Pet. Ex. 3 at 1. The Intake Comments Section states, "c/o right upper arm pain right deltoid area caving in onset this morning received flu shot one week ago." *Id.* Under "History of Present Illness," it states, "This 48-year old female presents with 1. shoulder pain/injury. Onset 3 to 5 days ago. It occurs constantly and is stable. Location: right shoulder….The pain is aching." *Id.* The provider, a Physician Assistant ("PA-C"), observed a "lesion" that appeared on petitioner's right shoulder and wrote, "The type of lesion is fat wasting." *Id.* at 3.

Petitioner took a picture of her shoulder on October 23, 2017. Pet. Ex. 19 at 1. The next day, October 24, 2017, petitioner returned to her PCP regarding her "arm pain and the indention." Pet. Ex. 1 at ¶ 8; Pet. Ex. 2 at 3. The reason for the appointment states "[i]ssue with flu shot site." Pet. Ex. 2 at 3. Under History of Present Illness, it notes an "Upper Extremity Injury," and explains that "patient was here 10/5/2017 for a flu shot and was given Fluzone Quad (Route: Intramuscular) on right deltoid." *Id.* Further, the record notes that petitioner "was seen at UCGC today and told she has 'fat wasting' as a result of the flu shot and she needed to be seen here immediately." *Id.* Petitioner reported that she "went to take a shower, [and] states her arm started getting numb." *Id*. Additionally, petitioner reported that her arm is sore and warm to touch and that her arm was so sore, she could not sleep on it. *Id.* Dr. Collier examined petitioner's arm and observed a "large indentation on right upper arm." *Id.* He also wrote, "No fluctuance. No redness, heat, nor [tenderness to touch]. [Full range of motion]." *Id.* at 4. The same day petitioner presented to a gastroenterologist related to her anemia, and under musculoskeletal review of systems, petitioner reported having "joint pain." Pet. Ex. 7 at 33.

On November 1, 2017, petitioner received a B12 injection. Pet. Ex. 11 at 1. The medical record for this injection does not exist. On December 14, 2017, petitioner returned to Urgent Care with "cold symptoms," and under musculoskeletal it lists "myalgia." Pet. Ex. 3 at 5-6. Petitioner explained that she "suddenly developed flu-like symptoms, fatigue, nasal congestion, some difficulty breathing and fever." Pet. Ex. 1 at ¶ 11-12. Petitioner explained she felt "weak, fevered and experience[ed] breathing and congestion." *Id*. The flu-like symptoms continued until on January 24, 2018, when petitioner was seen by Dr. Collier for "flu-like symptoms." Pet. Ex. 2 at 1. Petitioner's rapid flu A and B tests were negative. *Id.* He prescribed her Allegra D

for sinus congestion and recommended that she use over-the-counter medication for fever or pain. *Id.*

Petitioner returned to urgent care on February 12, 2018, presenting with "sinus symptoms [and] diarrhea." Pet. Ex. 3 at 9. A rapid Flu test was negative for Flu A and positive for Flu B. *Id*. The doctors prescribed rest, fluids and over-the-counter medication to treat her fever. *Id*. at 12. On February 14, 2018, petitioner visited Dr. Hardage for "right shoulder." Pet. Ex. 5 at 1. Under History of Present Illness, it states,

> 48-year-old female with no history of previous shoulder issues who presents today with pain and abnormality of her right shoulder. She states that in October she received a flu vaccination in her right deltoid and over the next couple of days she developed swelling and pain and then noted an indention in the lateral aspect of her shoulder. She has progressively worsening pain with any reaching away from body or overhead; indention and atrophy has increased. No numbness or tingling. No radiation of pain down the arm. She has pain with lying on her right side, no pain with sitting and resting her arm.

Id.

In the same record, the musculoskeletal section is marked, "yes" for "painful joints," "muscle weakness" and "joint stiffness." Pet. Ex. 5 at 1. The physical examination of her right shoulder revealed, "…atrophy and soft tissue indention along the lateral aspect of her right shoulder just below the acromion with some prominence into the upper arm below" and that "…she has a few degrees of abduction for flexion due to pain, she has positive impingement signs, she has weakness with external rotation of the shoulder, mild weakness in the supraspinatus, no laxity, her hand and arm are neurovascularly intact." *Id*. at 2. Petitioner demonstrated a full range of active motion but was "tender to palpation along the supraspinatus and subacromial bursa." *Id.* at 2. Petitioner was positive for Hawkin's and Neer's test, negative for Yergason's, empty can test, and O'Brien's test. *Id*. Under Assessment, petitioner was diagnosed with "rotator cuff syndrome of right shoulder [and] right shoulder pain, unspecified chronicity…SIRVA Vaccination injury." *Id*. Under "Notes," Dr. Hardage wrote, "[Petitioner] had a flu vaccination to her right shoulder and has most likely sustained a SIRVA vaccination injury. She does have irritation [of] her rotator cuff and some capsulitis and we will get her started in physical therapy to work on range of motion and strengthening." *Id.* at 3. Dr. Hardage also ordered petitioner to have an MRI of her right shoulder. *Id.*

On February 14, 2018, petitioner underwent an MRI of her right shoulder. Pet. Ex. 4. The MRI found "mild intrasubstance intermediate signal within the intra-articular portion of the tendon" on the biceps tendon and "mild diffuse intrasubstance intermediate signal within the distal supraspinatus and infraspinatus tendons." *Id.* at 2. The impression was, "tiny low-grade partial thickness, bursal surface tear of the distal supraspinatus tendon superimposed on mild supraspinatus/infraspinatus tendinosis," and, "small region of age-indeterminate partial-thickness split type tearing/fissuring of the upper distal subscapularis tendon." *Id.*

Petitioner was recommended physical therapy, and participated in physical therapy from February 19, 2018, through April 12, 2018. Pet. Ex. 1 at ¶ 12-15; Pet. Ex. 6 at 28. During the initial visit it notes that petitioner was "diagnosed with SIRVA vaccination." *Id*. Petitioner reported "numbness in her fingers…a couple of days after the injection." *Id*. at 30.

On February 20, 2018, petitioner returned to Dr. Hardage to discuss the initial MRI, and under assessment it lists "rotator cuff syndrome of right shoulder…SIRVA Vaccination Injury." Pet. Ex. 28 at 21-22. Petitioner's right shoulder was tender to palpation along the supraspinatus and subacromial bursa and she demonstrated positive Hawkin's and Neer's tests. *Id.* at 21.

On March 20, 2018, petitioner revisited Dr. Hardage where they discussed her ongoing physical therapy. Pet. Ex. 28 at 23-38. Petitioner reported that she was "having no pain at this point," and that she was "quite pleased with [her] progress." *Id.* Dr. Hardage noted that petitioner's range of motion had improved. *Id.* He did note that she had an "indention and atrophy into her right shoulder from her vaccination injury," and that "cosmetically this bother's her a lot and she is very frustrated with this…." *Id.* An inspection of the right shoulder was consistent with prior examinations. *Id.* at 24. Dr. Hardage wrote, "[Petitioner] has what appears to be atrophy and a fairly significant intervention into the subcutaneous tissues on the right side of the shoulder and into the subacromial space. She has excellent range of motion and strength in the shoulder. She has no instability." *Id.* He diagnosed petitioner with, "Rotator cuff syndrome of right shoulder. SIRVA Vaccination Injury." *Id.*

The physical therapy plan included 12 total sessions of physical therapy, and petitioner was discharged on April 12, 2018. *Id*. at 1, 32; Pet. Ex. 4 at 3. The assessment for the last physical therapy session notes that "she was preparing to have a PRP [Platelet-Rich Plasma] injection to see if it helps with her muscle atrophy." *Id*. at 2. Dr. Hardage performed the PRP injection on April 13, 2018, and under examination it notes "full range of motion, excellent strength, she has atrophy and sunken defect into the right lateral shoulder." *Id*.

On May 10, 2018, petitioner revisited Dr. Hardage to recheck petitioner's shoulder following the PRP injection. Pet. Ex. 28 at 28-29. Petitioner reported a little improvement in the lower portion of the atrophied area on her right shoulder since the PRP injection, but she was not having any pain with movement. *Id.* at 28. On June 11, 2018, petitioner took two pictures of her right shoulder. Pet. Ex. 19 at 3-4. On June 5, 2019, petitioner took a picture of her right shoulder. Pet. Ex. 19 at 2.

Petitioner returned to Dr. Collier for a wellness exam on October 19, 2018, and had no complaints related to her right shoulder, she received a flu vaccine in her left deltoid and a B12 injection in her right deltoid. Pet. Ex. 18 at 10-14. On January 4, 2019, petitioner received another B12 injection, this time in her left arm. *Id.* at 5. On May 7, 2019, petitioner received another B12 injection, but this time on her left hip. *Id.* at 1.

c. Hearing Testimony and Affidavits/Statements

1. Testimony of Petitioner, Mrs. Dee Ann Quantie

During the hearing held on November 8, 2021, petitioner testified that on Thursday, October 5, 2017, she went to this doctor's office and received a flu vaccine in her right arm and a B12 shot in her left arm. Transcript ("Tr.") at 60-61. Petitioner is right hand dominant. *Id*. at 65. During cross examination, she testified that on Friday, October 6, 2017, her right arm was "hot to the touch [and] there was swelling…around the injection site." Tr. 72. Petitioner testified that the same day she observed the indentation in her arm, and that it "got wider and deeper over time." *Id*. at 72-73.

Petitioner testified that she had received the vaccination from a nurse. Tr. 69. She testified that she did not remember the nurses name but had received prior injections from the nurse. *Id.* When asked by respondent's counsel if petitioner had any issues from prior injections she received, petitioner responded that she had not. *Id.* Petitioner did recall that she was sitting down at the time she received the vaccination at issue. *Id.*

The days following the vaccination petitioner explained that her arm was "sore and it was hot to the touch and it was just red, swollen," and she experienced "shooting pain in [her] arm, and this went on for a day or two and then it started getting worse." Tr. 61. During cross examination she explained that she would take Aleve for pain relief. *Id*. at 75. Petitioner called the doctor and the nurse told her "it just could be a reaction." *Id*. Further, she testified that there was "an 'indention' in my arm…and then days had passed and I'm trying to bathe, do my hair, and I noticed that my arm was getting weaker. I was dropping things. " *Id*.

When petitioner returned to the doctor's office on October 19, 2017, for issues related to her anemia and regarding her shoulder pain, she stated that the doctor told her, "it could be just a reaction, so just give its some more time." *Id*. at 62. Further, she testified that the doctor stated, "that possibly that the shot was not given in the right spot and that this could just be a reaction. He told me to watch it and if it gets worse, that I could go for further advice or treatment or contact him back, and that's what I did." *Id*. During cross examination, she explained that during the appointment she was having a "hard time using [her] arm," and "had a hard time raising [her] arm over [her] head." *Id*. at 79-80.

Petitioner testified that on October 22, 2017, she went to urgent care for her shoulder and explained that the provider recommended talking to an orthopedic specialist and to "contact your family doctor and let him know what is going on." *Id*. at 63. She returned to Dr. Collier and gave petitioner exercises for her shoulder, and she told him she felt "like I'm losing my arm…like I'm losing the pressure in my arm." *Id*. at 63-64.

On October 23, 2017, petitioner took a photo of her right arm, and was directed to view the picture during the hearing. Pet. Ex. 19 at 1; Tr. 65. Petitioner testified that she took the photo because "people wanted to see this is what happened and this is where I got the flu shot." Tr. 66. Petitioner explained that prior to the vaccination, she had no difficulties with her right arm and was "fully functional…able to participate in activities like church outings, playing with my grandchildren." Tr. 58-59.

Petitioner testified that she was required to get regular B12 shots once a month, since the summer of 2008 and received one prior to the vaccination in question in September 2017. Tr. 59-

60. Petitioner never had complications from the B12 shots, including the September 2017 B12 shot in her right arm. *Id*. at 60.

During the hearing she was asked what symptoms she still has to this day, and she explained that "I still hurt. I used to be able to dress professional for the part…I used to be able to curl my hair, style my hair. I used to be able to dress myself. I still can dress myself occasionally. It just depends on the day. Some days are better than others; some days aren't." Tr. 64. Petitioner explained she "literally had to change my identity," and her 16-year-old granddaughter will assist her with daily tasks such as styling her hair. *Id*. Further, she testified that she has "learned to deal" with the symptoms. *Id*. at 65. The Court asked petitioner about how petitioner's arm was after physical therapy and at the time of the hearing, she responded that "it was about the same." *Id*. at 93. Further, the Court asked about the exercises she completed at physical therapy and she explained that she used a rubber band ("Theraband") to exercise her shoulder and demonstrated that she stretches it "out at waist level and then it took…to shoulder level." *Id*. at 95. During the demonstration it was noted that petitioner was able to lift her left arm higher than her right arm. *Id*. at 95-96. Further, petitioner testified that if she applied pressure to the impacted shoulder in the indentation that it was still swollen, warm to the touch, and was painful. *Id*. at 96-97.

Petitioner testified that she told her co-workers what occurred, and she state that her co-workers "knew something was wrong when I was having issues carrying the mail bins, trying to type cand my hand would go to sleep and my arm would hurt, or trying to carry folders." Tr. 65.

2. Testimony of Staci Grammar

Ms. Staci Grammar, petitioner's co-worker, testified that she had known the petitioner for 15 years. Tr. 4. She testified that before the vaccination she did not "observe any difficulty" with petitioner's arm. Tr. 5. Ms. Grammar testified that she recalled petitioner showing her arm within a couple of days of the vaccination and "there was this odd sunken-in spot…and it was bruised and a reddish color." *Id*. Further she testified that "it was just very painful." *Id*.

Further, Ms. Grammar testified that she observed that the petitioner was "having a hard time raising her arm and lifting anything heavy." Tr. 6, 19. She noted that in their office environment they had to often "carry folders and boxes, but she was not able to keep doing that." *Id*. Petitioner mentioned to Ms. Grammar that "she has to have help drying her hair or styling her hair because just holding her arms up over her head in that way is just not feasible for her." *Id*. at 7, 19. Further, Ms. Grammar testified that petitioner has "continued to struggle with it." *Id*. at 7-8.

During cross examination, Ms. Grammar testified that she did not recall if petitioner ever texted her about her symptoms and she did not have any written documentation about the symptoms petitioner was describing. Tr.11-12. However, she testified that when petitioner complained about her right shoulder, she did so in person with Ms. Grammar. Tr. 15. Ms. Grammar testified that petitioner first complained about her shoulder pain "within a couple of days," and that she would have seen the shoulder on the day she first complained about the pain. *Id*. at 14-15. Further, Ms. Grammar stated that she recalled seeing petitioner's shoulder and it

was "a sunken spot that [she] had never seen before on anyone," and that "it didn't look normal for sure." *Id.*

3. Testimony of Barbara Groberg

Ms. Barbara Groberg executed a witness statement on April 24, 2018, and it was filed on June 11, 2018. Pet. Ex. 14 (ECF No. 9). Ms. Groberg, petitioner's co-worker, has known Mrs. Quantie since November 2016, and worked with her through January 2021. Tr. 42, 47. Ms. Groberg stated that she worked with petitioner five days a week in October 2017. Tr. 49. She testified that before the vaccination Mrs. Quantie had no issues with her right shoulder prior to October 2017, she helped "lifting boxes of copy payer to fill copiers and boxes of folders receiving in the mail and tubs of mail." *Id*. at 43. During cross examination, Ms. Groberg explained that in her role as petitioner's supervisor, she remembered the date of the vaccination because she would "verify her time and attendance through our time and attendance system at work and Dee Ann is very infrequently away from work." Tr. 50. In her statement she explained that "most employees will opt to receive their flu shot at work when we have contractors in the office one day each fall to provide this service. Dee was not here that day, and I recall her stating she would get the shot at her physician's office." Pet. Ex. 14 at 1.

Following the vaccination in question, Ms. Groberg testified that "within a couple of days after…I remember her saying her arm was quite sore…more than just after a normal flu shot…it progressively got worse and worse." *Id*. at 44. Ms. Groberg stated that petitioner complained of the pain starting "within days…a close association to that time." *Id*. During cross examination, Ms. Groberg again testified that petitioner first complained of shoulder pain "within a couple of days." *Id*. at 50. She stated that there was "a remarkably large lump on there. It was very swollen…she was in a lot of pain." *Id*. During cross examination, she confirmed that she visualized petitioner's shoulder and "it was alarmingly swollen." *Id*. at 51.

Later, Ms. Groberg testified that a few months after the vaccination petitioner's ability to use her arm was "impaired," because "she had trouble lifting the arm," and "impeding just daily activities or daily appearance." Tr. 45. She wrote that petitioner's "upper arm has continued to appear to deteriorate, presenting a concave appearance." Pet. Ex. 14 at 1. She stated that petitioner "wasn't able to like physically lift anything probably more than five or ten pounds." *Id*. at 46. She also testified that petitioner is not one to complain and if she was "saying something hurts or is bothersome, it really must hurt." *Id*. During cross examination, Ms. Groberg further explained that "there are things that would bother a lot of people I know in terms of, you know, the amount of pain or discomfort someone's in and she never complains." *Id*. at 50. Further, during cross examination Ms. Groberg explained for petitioner "not to be able to carry out those tasks was also very frustrating for her, I could tell." *Id*. at 56.

Ms. Groberg explained that employees in the office take turns sorting the mail, and that prior to the vaccination petitioner "was always very helpful in doing the mail and she's always very quick and efficient…I remember her not being able to do that just because there was so much of it and that repetitiveness and using that arm, it just was really bothersome for her." *Id*. at 46. She testified that from October 2017 through January 2021, Ms. Groberg observed "weakness in that arm even after the swelling went down and …a concave – like a dent in her

arm." *Id*. at 47. As a result of the pain and weakness, Ms. Groberg testified that petitioner "opted for like a low maintenance kind of haircut or would wear ball caps just to eliminate," lifting her shoulder. *Id*

4. Testimony of Kaylee Grimm

Ms. Kaylee Grimm, petitioner's daughter, executed a witness statement on April 21, 2018, and it was filed on June 11, 2018. Pet. Ex. 11 (ECF No. 9). Ms. Grimm testified that prior to the vaccination petitioner was "doing really well. She was very functional. She had no problems, no injuries…she was completely normal." Tr. 23. When the Court asked Ms. Grimm about petitioner's shoulder prior to the vaccination, Ms. Grimm testified that "she had no problems whatsoever." Tr. 40. At the time of the vaccination Ms. Grimm was not living with petitioner, but at the time of the hearing she was living with her "trying to help her out" because of her injury. *Id*. at 23-25. She explained that a "couple days" after receiving the vaccination petitioner "was complaining that she was in a lot of pain and she just couldn't do things like she normally could. She was hurting." Tr. 24. Ms. Grimm wrote in her witness statement that petitioner "was complaining the next day that her shoulder was swollen and hurting." Pet. Ex. 11. Ms. Grimm testified that petitioner "had a hard time doing her daily activities, just like changing diapers, doing dishes, having a hard time getting dressed because of the pain. Tr. 24. She just couldn't do anything. And she still to this day is having a hard time." *Id*. She stated that a few days following the vaccination she saw petitioner's arm and explained that "there [was] a huge 'indention' in it. It just looked like it was pulling apart, like the muscle was pulling apart." *Id*. at 25.

Ms. Grimm stated the petitioner "is still struggling," and that Ms. Grimm still has to "help her do her hair in the morning…she has a hard time fastening anything, getting things over her shoulder. She just doesn't' have the strength sand says she's in a lot of pain." Tr. 24-25.

During cross examination, Ms. Grimm explained that she saw her mother two or three days after she received the vaccination, and "maybe a week, a week and a half" later when Ms. Grimm accompanied petitioner to a doctor's appointment. Tr. 30, 33. Besides the "indention," Ms. Grimm also explained that petitioner's shoulder "was really warm to the touch. Like it almost had like heat coming off of it." *Id*. at 34. Ms. Grimm testified that petitioner "complained big-time if anybody touched it," and that it was visibly red. *Id*. When she was asked how large the "indention" is, she replied that "I could probably fit two of my fingers in the area where it indented at," and it was "an inch or half an inch" deep. *Id*. at 35. She testified that petitioner was "extremely concerned and almost scared…she was nervous," directly following the vaccination. *Id*. at 38.

5. Statement of Jamie Rush

Mr. Jamie Rush, petitioner's coworker, filed a witness statement on June 11, 2018. Pet. Ex. 10 (ECF No. 9). Mr. Rush did not testify at the entitlement hearing. He stated that petitioner came to work on October 9, 2017, four days after the vaccination, and he observed petitioner's right shoulder with a "red, swollen and bruised area on the upper part of her right arm near her

shoulder." *Id*. He stated that petitioner was complaining about the pain that day and that "she could hardly use her arm." *Id*.

Mr. Rush stated that on October 13, 2017, petitioner asked him to look at the vaccination site and he "still noticed bruising, in addition, there was an obvious dent on the area about the size of a quarter." *Id*. Further, he stated that petitioner has shown her arm "several times and the dent has become larger and deeper looking as though the skin had literally sunk to the bone." *Id*.

6. Statement of Kelsie Grimm

Ms. Kelsie Grimm, petitioner's daughter, executed a witness statement on April 20, 2018, and it was filed on June 11, 2018. Pet. Ex. 12 (ECF No. 9). She stated that following the vaccination petitioner "had been complaining for a couple of days that her right arm and shoulder had been hurting her from the flu shot." *Id*. Ms. Grimm recalls observing her mother's arm as "red, swollen and bruised." *Id*. She recalled her "mother could hardly grasp her brush to comb her hair her arm was swollen, she called her local doctor and was told by the nurse that there was nothing that could be done." *Id*.

III. Expert Opinions Regarding Vaccine Causation

a. Petitioner's Expert Opinion on Causation, Dr. Marko Bodor

Dr. Marko Bodor submitted two expert reports on behalf of petitioner and testified at the hearing. Pet. Ex. 20 (ECF No. 31); Pet. Ex. 27 (ECF No. 40). Dr. Bodor opined that "based on the location of the atrophy and the weakness in external rotations…the vaccination was administered into the teres minor or infraspinatus tendons." Pet. Ex. 20 at 2. Dr. Bodor opined that "she has persistent loss of passive range of motion, consistent with a mild degree of frozen shoulder, which has been described in association with SIRVA." *Id*. Dr. Bodor testified that based on petitioner's history "it does appear that she has a SIRVA injury." Tr. 145.

Dr. Bodor testified that the definition of SIRVA is a "medical legal term which implies that someone had a vaccination which led to chronic pain in the shoulder more than six months, but it can also be described for an acute injury, too." Tr. 110. From his clinical practice, he explained that patients who have incurred a SIRVA-type injury following vaccination typically do not go to the doctor immediately "because they expect that the pain is just normal or variant and it's just going to go away." *Id*. at 111. During cross-examination he testified that the incidence of SIRVA "is somewhere between 1 out of 10,000 and 1 out of 100,000." Tr. 148. He described the proper vaccination technique "would be to inject the vaccine in the middle part of the deltoid muscle," from the top of the shoulder to halfway down the arm in the deltoid muscle, so the vaccine should be injected "in the middle of that." *Id*. at 111-112. He explained during cross-examination that "for 95 to 99 percent …of patients," the mechanism of SIRVA injury is going to be an injection that's both too high and too deep in the shoulder," and that is what occurred in petitioner's case. *Id*. at 148-149. While petitioner testified she was seated for the vaccination, Dr. Bodor opined that being seated doesn't automatically mean it was misadministered. *Id*. at 113. He stated that "as long as you're in the middle of the deltoid,

whether you're injecting at zero degrees or 45 degrees, you're not going to migrate that far from the perfect target." *Id*.

Dr. Bodor demonstrated that if a vaccination is administered too high on the shoulder, the deltoid muscle is thinner and could "easily overpenetrate, that means go through the deltoid muscle and into the bursa, which is underneath your muscle, or the rotator cuff, which is underneath the bursa, or the capsule, which is underneath the rotator cuff, or the bone, which is right there, or even the joint depending on where you are there." Tr. 114. He opined that contrary to his 2007 paper the most common way for the vaccine to go is "not the bursa," but "the actual cuff itself, and then from there, it's going to gravitate into the bursa and in other directions." *Id*. at 115. He testified that the "bursa is, on average, 11 millimeters, range, 8 to 16 millimeters." *Id*. During cross-examination Dr. Bodor testified that "we can see based on where the atrophy is, that's too high." Tr. 149. He stated that the area of lipodystrophy on petitioner is "in the top one-third of the shoulder," and the "rotator cuff tendons go down 3 centimeters to 6 centimeters, depending on how tall you are, from the acromion. From 3 to 6 centimeters, there can be, in this area, your tendons. The teres minor may be as low as 6 centimeters below the acromion in tall men who are 6 feet tall. So you should not be in the top 6 centimeters." Tr. 150. He stated that in petitioner's case "it's in the top 6 centimeters of the" shoulder. *Id*. at 151.

Dr. Bodor testified that the injury is not a mechanical one, "it's not the needle going into the cuff that injures it, it's just the vaccine itself that causes pain." *Id*. at 115. He explained there are two mechanisms for pain, the first "is there can be a direct nociceptive response, meaning direct pain response to the nerve fibers that are in there," this is immediate. *Id*. at 116. The other mechanism is a delayed response "mediated by the immune system," which occurs 24 to 48 hours later. *Id*. He testified that, "it's either persistent antigens that are there or persistent immune response caused by the antigens…and the antigens are likely bound in that collagen or bound within the fibers of the tendon and the immune system is attacking the tendon, thinking that there's an infection there." Tr. 116.

Using an image entitled "Rotator Cuff Muscles & Tendons," Dr. Bodor explained that "the shoulder as it looks underneath the deltoid muscle…depicting some of the rotator cuff tendons, supraspinatus, subscapularis, and also the biceps brachii." Tr. 117. The image demonstrates that the "white represents less blood, because red is where there's hemoglobin. There's more blood supply. White is more collagen and less vascular, meaning there's not as much blood in there." *Id*. In Dr. Bodor's practice, injuries to the infraspinatus tendon happens 45% after vaccination, and injuries to the teres minor tendon also happens 45% after vaccination. *Id*. at 118. Dr. Bodor explained that the reason the posterior tendons make up the majority of SIRVA's because if the vaccination is administered "too high, they're going to get that tendon, either the teres minor or the infraspinatus." *Id*. at 119. By using the picture that petitioner took of her right shoulder on October 23, 2017, Dr. Bodor opined that the shot was given "too high…[and] it would need to go below that." Tr. 144.

In response to Dr. Abrams expert reports, Dr. Bodor opined the location of the lipodystrophy "is approximately 3-4 cm distal to the lateral edge of the acromion…[and] this location should be avoided for vaccinations and other injections. Pet. Ex. 27 at 1. Citing to his own article, Dr. Bodor explained that he researched the length and type of needles used in

influenza and pneumococcal vaccine injections.[5] Pet. Ex. 22; Tr. 125. During cross-examination he explained that the study found increased signals in the teres minor which was evidenced through an MRI. Tr. 174-175. He testified that the common length of needles used for influenza vaccination is 1 inch or 2.5 centimeters, and the length between the skin and the bursa is approximately 1.1 centimeters to 1.3 centimeters. *Id*. at 126. Further, the article indicated that the distance between the skin to the subdeltoid bursa is "1.2 cm for female[s] and 0.6 cm for male[s]." Pet. Ex. 22 at 2. Dr. Bodor stressed that the deltoid muscle is the thinnest near the top of the arm. Tr. 124-125.

During the hearing, Dr. Bodor cited to the *Atanasoff* article to explain that at the time of the paper's publication a SIRVA could occur when the needle "goes through the subacromial bursa and goes into the rotator cuff," which is "well within the 3-6 cm range distal to the acromion" which is where they noted the location of the bursa and rotator cuff in 21 healthy volunteers in a study done by Dr. Bodor and his colleagues.[6] Pet. Ex. 27 at 1; Tr. 122. Further, he testified that "the bursa is 1 millimeter and the tendon is about 3 to 4 millimeters in thickness," and "if you're coming in with a needle, it's not likely that you're going to just go through the muscle and you're going to stop right at the bursa, which is 1 millimeter and then you inject everything there." *Id*. Using the *Barnes* article, submitted by respondent, Dr. Bodor explained an image from the article to show that the deltoid muscle gets thinner closer to the top of the shoulder.[7] Resp. Ex. A Tab 10; Tr. 124.

Dr. Bodor stated that petitioner's complaints are not consistent with just a diagnosis of lipodystrophy. Tr. 145. Regarding the lipodystrophy, Dr. Bodor explained that "lipoatrophy or lipodystrophy is a condition that can arise from an injection, any kind of injection, it doesn't have to be a vaccine…and it's a condition that causes a change in the normal structure of the fat in the area." Tr. 128. Lipohyertorphy means the "enlargement of fat," and lipoatrophy means the "shrinkage" of fat. *Id*. Dr. Bodor stated that the lipoatrophy is in the subcutaneous fat layer, which can be "very thin or nonexistent…up to a centimeter or bigger." *Id*. at 129. He opined that lipoatrophy is a dermatological issue and is not associated with acute shoulder pain, or loss of range of motion. *Id*. Dr. Bodor opined that petitioner "had lipodystrophy there before. Now, on top of that, we have this acute reaction from the vaccine, which probably went in a few places in there, and now the combination of the preexisting lipodystrophy and the acute inflammation may have…made it more noticeable." Tr. 131-132. Dr. Bodor stated that the petitioner had "two separate distinct issues," the first is lipodystrophy and the "vaccine-related pain dysfunction, which we call SIRVA." Tr. 132, 152. During cross-examination he opined that petitioner's lipodystrophy was caused by her prior B12 injections, and the flu vaccine was "a contributor but not the primary cause." Tr. 169-170. He stated that "there is reason to believe that her prior lipodystrophy was something that she didn't notice, and then when the flu vaccination went in there, it caused some additional inflammation and it caused her to notice it." Tr. 170.

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[5] Marko Bodor & Enoch Montalvo, *Vaccination-related shoulder dysfunction*, 25 Vaccine 585-587 (2007). [Pet. Ex. 23].

[6] S. Atanasoff, et. al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049-8052 (2010). [Pet. Ex. 26].

[7] Matthew G. Barnes, et. al., *A "Needling" Problem: Shoulder Injury related to Vaccine Administration*, 25 J. of the Amer. Board of Family Med. 6, 919-922 (2012). [Resp. Ex. A Tab 10].

Dr. Bodor opined that "the injection went through the area of the lipodystrophy, in through the deltoid muscle, and went in her rotator cuff. And from there, most of it was deposited there, but some of it may have leaked out back along the shaft of the needle into the area of the lipodystrophy." Tr. 133. He concluded his testimony by stating that in this case "the needle went through the deltoid muscle and into the rotator cuff…and some of the vaccine was deposited there, some of it leaked out, and it caused a persistent inflammatory reaction or nociceptive reaction." *Id*. at 135.

Regarding the onset of pain and the length of time petitioner waited to seek treatment, Dr. Bodor wrote that "the fact that shoulder symptoms were not initially documented in the medical record does not mean that [petitioner] did not have shoulder pain at that time." Pet. Ex. 27 at 1. He argued that petitioner was seeking medical advice on her anemic condition, and therefore the "normal" notation under musculoskeletal exam is "not an entry reflecting that Dr. Collier actually examined her shoulder." *Id*. at 2. He testified that petitioner's medical records and testimony confirm that days following the vaccination in question she began to develop symptoms and "complains of progressively worsening pain with reaching away from her body or overhead." Tr. 135-136. During cross-examination, he stated that petitioner's symptoms began within 48 hours after vaccination, and that was corroborated by petitioner and the other witnesses along with "the orthopedic surgeon." Tr. 152. Dr. Bodor testified that the progressively worsening pain is common in SIRVA injuries because "when you reach up and forward, you're going to activate the rotator cuff muscles and tendons. And since the likelihood is that there was deposition of vaccine in one of her rotator cuff tendons, that would have caused pain." *Id*. at 136.

Dr. Bodor stated that the Hawkins test is an "impingement test," in which the patient would move their arm across their body at shoulder level and the Neer's test is an "abduction" test while reaching straight up. Tr. 137-139. Dr. Bodor opined that an individual with lipodystrophy would not have a positive Hawkins test or Neer's on the basis of lipodystrophy alone. *Id*. at 139-140. Dr. Bodor explained that petitioner had positive Hawkins test and Neer's test on her right shoulder, and negative on her left shoulder. Tr. 140; Pet. Ex. 5 at 2. Citing to the medical record, Dr. Bodor testified that petitioner exhibited numbness and tingling, a consistent symptom of a SIRVA injury. Tr. 141.

He analyzed the medical records from October 22, 2017, and argued that the Urgent Care notations involving onset were likely incorrect and also contains another incorrect statement "that she received a flu shot 'one week ago' when we know it was provided two and a half weeks prior." Pet. Ex. 3 at 1-3; Pet. Ex. 27 at 2. Additionally, while Dr. Abrams argues that Dr. Collier's exam of petitioner's shoulder was normal that same day, it directly contradicts the urgent care records from earlier that day. *Id*. at 2. Further, Dr. Bodor read petitioner's medical records from February 14, 2018, which showed "rotator cuff syndrome of right shoulder…right shoulder pain, unspecified chronicity….SIRVA Vaccination Injury." Pet. Ex. 5 at 2; Tr. 141. Dr. Bodor stated that the treating orthopedist "wrote that there was some supraspinatus and infraspinatus tendinopathy." Tr. 141. Dr. Bodor further testified that petitioner's visit to the orthopedist on February 20, 2018, reconfirmed petitioner's diagnosis with a SIRVA injury under assessment, "rotator cuff syndrome of right shoulder…SIRVA Vaccination Injury." Pet. Ex. 28 at 21: Tr. 143.

b. Respondent's Expert Opinion on Causation, Dr. Geoffrey Abrams

Dr. Geoffrey Abrams submitted two expert reports on behalf of respondent on January 12, 2020, and May 1, 2020. Resp. Ex. A (ECF No. 37); Resp. Ex. C (ECF No. 43). Dr. Abrams was admitted as an expert in the field of orthopedics and orthopedic sports medicine. Tr. 201. Dr. Abrams opined that "the timing and clinical presentation of the symptoms do not lead to the conclusion that the influenza vaccination 1) caused the lipoatrophy nor 2) led to any other shoulder pathology." Resp. Ex. A at 7. Further, he wrote in his first expert report that its "very plausible that the lipoatrophy itself, which per the above facts is unlikely to be related to the vaccination, could be the cause of her clinical symptoms." *Id*.

Dr. Abrams testified that petitioner's history of B12 injections was the cause of her lipodystrophy, not the flu vaccine. Tr. 204. Respondent pointed to various articles that B12 injections "are well documented cause of lipoatrophy and/or scleroderma." Resp. Ex. A at 4. (Ho, Kennedy, Burns). Therefore, he opined that petitioner received B12 injections "to the right shoulder nearly every month for the six months preceding the vaccination in question…[therefore] these injections, particularly multiple injections over many years, could certainly be a contributing factor to petitioner's lipoatrophy and associated pain." Resp. Ex. A at 5. He further testified that "lipoatrophy can be a cause of pain…it's not common, it is certainly possible for lipoatrophy itself to cause pain." Tr. 205. Dr. Bodor stated that "when we have atrophy of tissues or other insults, it's almost always an inflammatory process…so it would make sense and it would seem very acceptable to acknowledge that fact that an inflammatory process such as lipoatrophy can cause pain in the skin." *Id*. at 206.

Quoting Dr. Bodor, Dr. Abrams testified that a SIRVA is "an inflammatory reaction from the vaccine deep within the shoulder…it can go into the rotator cuff, the subacromial space, bursa, [or]…into the bone if the needle hits the bone." Tr. 207-208. Dr. Abrams testified that "the injection is put deep within the shoulder and that's the whole crux of the SIRVA contention is that the vaccine and the inflammatory components are put deep within the shoulder to the deeper structures." *Id*. at 208.

Citing to the *Kennedy* article, Dr. Abrams explained that "localized sclerodermoid skin reactions have been reported at the site of intramuscular injections of B12."[8] Resp. Ex. A at 5; Resp. Ex. A Tab 2. Further, *Kennedy* found "intramuscular injection…has been followed by an erythematous plaque…which takes on a dusky colour and becomes infiltrated and itchy," and Dr. Abrams opined that that description is "consistent with petitioner's symptoms." *Id*. Dr. Bodor also cited to an article by *Ho*, which is a case report that found "local sclerodermoid change from multiple B12 injections…theorizing that it may be due to hypersensitivity to the vehicle or preservative within the B12 injection."[9] Resp. Ex. A at 5; Resp. Ex. A Tab 1. Dr. Abrams testified that "if we can accept the fact that in order for there to be shrinkage of the fat, there is an inflammatory process going on, which…is almost always a cause of pain, if she had pain in the

[8] Kennedy C., et. al., *Chapter 28: Mechanical and Thermal Injury*, 8 Rook's Textbook of Dermatology 44-45 (2010). [Resp. Ex. A Tab 2].

[9] Julia Ho., et. al., *Vitamin B12-Associated Localized Scleroderma and It's treatment,* 30 Dermatol. Surg. 9, 1252-1255 (2004). [Resp. Ex. A Tab 1].

skin, in the lateral deltoid, it can certainly reduce her desire to move her shoulder, it can limit her activities." Tr. 215.

Regarding the onset of petitioner's symptoms, Dr. Abrams opined that the medical timeline "documented in the medical record also does not support the conclusion that the vaccination in question may have caused pathology related to SIRVA." Resp. Ex. A at 5. Further, petitioner's medical encounters following the vaccination "suggest that there was no significant pathological process occurring around or within the shoulder, except for the lipoatrophy, which based on the above information was not related to the vaccination in question." *Id*. at 5-6. Dr. Abrams testified that "based upon the medical record with the urgent care visit of October 22, 2017, stating that she stated that [the pain] began three to five days prior to that, I would put it in the range of October 17 to 20 of 2017." Tr. 203. Dr. Abrams used Dr. Bodor's article and opined that the "symptoms should [have begun] much sooner than a number of weeks after the vaccination in question…some [patients] have reported symptoms within hours and this is supported in the literature." Tr. 203. Dr. Abrams testified that petitioner's first abnormal musculoskeletal exam was on February 14, 2018, therefore respondent "can rule out SIRVA if we accept the medical records." Tr. 213.

In response to Dr. Bodor's opinions regarding vaccine causation, Dr. Abrams stated that for "an injection to cause both lipoatrophy to the superficial tissues as well as damage to the deep underlying structures, such as the rotator cuff tendons, is extremely improbable." Resp. Ex. A at 6. Dr. Abrams agreed with Dr. Bodor that the most common needle length is "an inch-long needle…[or] 2.5 centimeters…and if you're too deep, you do get resistance." Tr. 209. Dr. Abrams testified that "there's other literature to show that the actual distance between the skin and the deep structure of the shoulder can be 2.5 centimeters or more in some instances…if we get resistance, we will withdraw it maybe a couple millimeters or so in order to get it back…we're not going to withdraw it so far that we inject the majority of the component into the subcutaneous tissue where the lipoatrophy is going on." Tr. 209-210.

In response to petitioner's argument regarding petitioner's "weakness in external rotation [as] evidence of injection into the teres minor or infraspinatus tendon," Dr. Abrams explained that external rotation weakness can be due to "generalized shoulder pain from prior injections and potentially, the resultant fat atrophy, normal age-related rotator cuff pathology, cervical pathology, viral mediated neuritis leading to weakness, among others." Resp. Ex. A at 6. Dr. Abrams opines that petitioner's MRI findings are "extremely common, even in patients without shoulder pain." *Id*. Further, he stated that petitioner's MRI was inconsistent with SIRVA, and that it is "possible that SIRVA exists without a demonstrable MRI finding…however, it makes it much less likely." Tr. 216.

Dr. Abrams cited to the *Yamiguchi* article, which found "that in over 500 patients who were presenting for unilateral shoulder pain, a majority had rotator cuff tearing (partial or full thickness) on their contralateral asymptomatic shoulder."[10] Resp. Ex. A Tab 6; Tr. 216. Dr. Abrams further testified that he sees "thousands of patients a year for their shoulder and…the

[10] Ken Yamaguchi et. al., *The Demographic and Morphological Features of Rotator Cuff Disease: A Comparison of Asymptomatic and Symptomatic Shoulders,* 88 J. Bone Joint Surg. Am., 8, 1699-1704 (2006). [Resp. Ex. A Tab 6].

majority of them, a great majority, are not able to identify a specific inciting event that caused their shoulder pain." Tr. 213-214. Citing to the *Reilly* article, Dr. Abrams explained that the study looked at cadavers and wrote about the "prevalence of rotator cuff pathology as we get older."[11] Tr. 226-227. He testified that he cited to this article to "support the concept that rotator cuff tearing is typical in the general population," and that "rotator pathology [is present] in a majority of people as we get older." *Id*. at 227.

Dr. Abrams referenced an article by *Uchida*, which discussed an individual with intense pain following vaccination with "inflamed fluid in the subacromial space and subacromial bursa."[12] Tr. 228; Resp. Ex. A Tab 11. He testified that the image in the *Uchida* article demonstrates a "fluid-sensitive sequence," in which "behind…the posterior aspect of the shoulder, which many vaccines get administered into, you can see the white that is on the bottom right portion of the ball. That white, similarly, is inflammation or inflammatory fluid that's collected, presumably in this case…due to the HPV administration." Tr. 229. Further he testified that no such fluid was found in this case. *Id*.

Dr. Abrams also cited to the *Okur* article to support his contention that if the injection had "involved the infraspinatus or teres minor tendons, we would expect to see evidence on this insult on MRI," and the literature supports the contention that "suspected SIRVA patients in their case series all had MRI findings of either bone, bruising, subacromial effusion, and/or fluid signal in the deep muscular layers."[13] Resp. Ex. A at 6. Dr. Abrams cited to the *Barnes* article to demonstrate that "there's almost always evidence of MRI findings suggestive of vaccine injury to the shoulder, and this case is no exception."[14] Tr. 217. When asked by the court about a figure demonstrating vaccine injury after reaching bone, Dr. Abrams stated that that injury "would be unusual," and SIRVA injuries are mostly generated because of some type of error in the injection process. Tr. 218-219. He conceded that the literature is generally describing the most clear cases of SIRVA because journal editors need "clear objective evidence that it actually happened." Tr. 219. He explained that the most common finding for a SIRVA "would be some type of subacromial inflammation or subacromial bursitis that would lead us to suspect that there is an inflammatory process going on in the shoulder. The inflammatory process on MRI would be reported as bursitis or inflammation." Tr. 220. Dr. Abrams testified that in this case "we don't see any of those findings…this is a less clear-cut case." *Id*. Dr. Abrams stated that the MRI findings in petitioner's case "are age expected and very common if we were to get MRI on a patient who is in their early forties…it does mention partial thickness tearing of the rotator cuff." Tr. 223. Dr. Abrams stated that she had "10 percent of the fibers that have actually pulled off the

[11] P. Reilly, et. al., *Dead men and radiologists don't lie: a review of cadaveric and radiological studies of rotator cuff tear prevalence*, 88 Am. R. Coll. Surg. 116-121 (2006). [Resp. Ex. 9 Tab A].

[12] Soshi Uchida, *Subacromial bursitis following human papilloma virus vaccine misinjection*, 31 Vaccine 27-30 (2012). [Resp. Ex. A Tab 11].

[13] Gokean Okur, et. al., *Magnetic resonance imaging of abnormal shoulder pain following influenza vaccination*, 43 Skeletal Radiol. 1325-1331 (2014). [Resp. Ex. A Tab 12].

[14] Matthew G. Barnes, et. al., *A "Needling" Problem: Shoulder Injury Related to Vaccine Administration*, 25 J. Am. Board. Fam. Med. 6, 919-922 (2012). [Resp. Ex. A Tab 10].

bone…the tearing is on the surfaces of the tendon and not inside the tendon," and he conceded that "it is possible" this type of injury would also be consistent with a SIRVA. Tr. 223-224.

When asked to describe the importance of the MRI finding of "mild intrasubstance intermediate signal," Dr. Abrams explained that "there's tearing within the substance of the biceps tendon…when you look at it in the shoulder, its literally a cylinder…she has partial tearing on the inside of that cylinder, so the tendon fibers that are within the pipe of the cylinder." Tr. 224-225. Dr. Abrams stated that "in order for the needle to get to the biceps tendon, there would have to be a hugely gross error in not only location of injection but also depth of penetration and needle length…the bursal surface of the rotator cuff or the subacromial bursa, which is just underneath the deltoid muscle. The biceps is double the distance away from any of those structures." Tr. 225. Dr. Abrams stated that if there was a vaccine injury to the bicep tendon he "would expect her to have much greater loss of range of motion, more problems with elbow flexion…a lot more problems…than [what] was reported in the medical record." Tr. 226.

IV. Applicable Legal Standard

To receive compensation through the Program, petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 300aa-13(a)(1)(A), 11(c)(1); *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

In this case, petitioner alleges both a Table Injury and, in the alternative, a causation-in-fact claim. As relevant here, the Vaccine Injury Table lists SIRVA as a compensable injury if it occurs within 48 hours of administration of a vaccine containing the influenza virus. § 300aa-14(a) as amended by 42 C.F.R. § 100.3(a). The Act's "Qualifications and aids in interpretation" ("QAI") provide specific guidelines used to evaluate Table Injury SIRVA claims. *See* 42 C.F.R. § 100.3(c)(10). To be considered a Table "SIRVA," petitioner must show: (i) there is "no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection"; (ii) that "onset of pain occurred within the specified timeframe," i.e. within 48 hours; (iii) that "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered"; and (iv) that "no other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG testing or evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." 42 C.F.R. § 100.3(a); 42 C.F.R. § 100.3(c)(10).

If petitioner can prove that her alleged injury meets these four elements, she will be entitled to compensation unless the government can show the injury was caused by a factor unrelated to vaccination. § 300aa-13(a)(1)(B). Petitioner bears a "preponderance of the evidence" burden of proof. § 300aa-13(a)(1).

The flu vaccine is a covered vaccine, and the Table specifies that for a Table SIRVA, onset must occur within 48 hours. *Id.* at §100.3(a)(VIII). Respondent argues that there is not

preponderant evidence demonstrating the requisite facts to establish compensation, specifically through the second and fourth QAI criteria. Resp. Pre-Hearing Brief at 21-25.

a. No history of pain, inflammation, or dysfunction of the affected shoulder.

Nothing in the medical record suggests that petitioner ever had any manifestation of pain or dysfunction in her right shoulder prior to the vaccination at issue. Her orthopedist, Dr. Steven Hardage wrote during an appointment on February 14, 2018, that she has "no history of previous shoulder issues." Pet. Ex. 5 at 1. Respondent's expert, Dr. Abrams testified that "there's no evidence [that]," petitioner had a prior history of pain in her affected shoulder prior to the vaccination. Tr. 242. Respondent has made no argument on this point, instead respondent merely points to the medical record of petitioner's various instances of receiving B12 injections since August 2013. Pet. Ex. 2 at 5; Resp. Pre-hearing Brief at 2. Petitioner received eight B12 injections in 2017 prior to the October 5, 2017, flu vaccination and nothing in the medical record demonstrates that petitioner had pain, inflammation, or dysfunction in the affected shoulder.

b. Pain occurs within the specified timeframe (48 hours).

Based on the record as a whole, I find that there is preponderant evidence that the onset of petitioner's shoulder pain was within forty-eight hours of her October 5, 2017, flu vaccination.

Respondent's main argument that petitioner did not have pain within forty-eight hours of the vaccination is that petitioner's first medical appointment about her right shoulder occurred 17 days after vaccination. Resp. Brief at 21. Respondent stated that "petitioner first complained of left shoulder pain at urgent care on October 22, 2017, seventeen days after vaccination, reported that the onset of her shoulder pain/injury began "3 to 5 days [a]go," which is approximately two weeks after vaccination. *Id.* Respondent asserted that, "petitioner has not filed any medical record, text, emails, or other contemporaneous record to refute this." *Id.* Respondent also argued that an intervening medical appointment, that occurred on October 19, 2017, there was no mention of right shoulder pain or dysfunction. *Id.* at 22. Respondent stated, "[d]uring an interval visit with her PCP, Dr. Collier, for anemia on October 19, 2017, two weeks after vaccination and three days before the urgent care visit, petitioner did not report shoulder pain or limited range of motion." *Id.* at 22; *see* Pet. Ex. 2 at 5-7. Respondent argued that the medical record from that date notes that petitioner's physical exam, "including musculoskeletal portion was "normal," with "no swelling or deformity." Resp. Brief at 22.

Then respondent asserted that petitioner's statements in her affidavit and the witness statements petitioner filed are unreliable and contradict petitioner's claims. Resp. Brief at 22. Respondent stated that "the witness statements claim that petitioner was complaining extensively about shoulder pain and showing her shoulder to family and coworkers," then argued that it "defies logic that petitioner had substantial shoulder pain and dysfunction, within forty-eight hours after vaccination, and that she neglected to report her condition to Dr. Collier in October. 19, 2017." *Id.*

The Vaccine Act provides that a special master may find the time period for the first symptom or manifestation of onset required for a Table Injury is satisfied "even though the

occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such a period." §300aa-13(b)(2). The Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014). The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).
The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

Petitioner persuasively testified that she experienced pain and swelling the day following the vaccination. Tr. 72. She testified that the next morning when she touched the injection site "it hurt." Tr. 73, 74. She stated that "she didn't think anything of it," because after she had received other flu shots "they would always hurt for a day or two and then they would go away." *Id.* Petitioner explained that the day following the vaccination, which was a Friday, and then into the weekend, her soreness became worse and it felt like a "weight on her arm." Tr. 73.

Petitioner also had multiple witnesses corroborate her testimony that her right shoulder pain began within the requisite time period. For example, Ms. Groberg, petitioner's supervisor at work, who interacted with petitioner "five days a week" in October 2017, testified that "a couple of days after [the flu shot], I remember [petitioner] saying her arm was quite sore…more than just after a normal flu shot." Tr. 44. Ms. Groberg stated that she asked petitioner about her arm a few days later and petitioner "lifted her sleeve…to show me and she had a remarkably large lump on there. It was very swollen. So I remember that pretty clearly. She was in a lot of pain." *Id.* When asked if she remembered the exact time petitioner's pain began after the flu shot, Ms. Groberg testified, "I don't remember exact dates since it's been quite awhile since this happened, but…it was, I think within days." *Id.* When respondent's counsel asked Ms. Groberg if petitioner complained of right shoulder pain to her the week following the Thursday, October 5, 2017 vaccination, Ms. Groberg stated, "Most likely…probably early the next week." Ms. Groberg's testimony does not conflict with petitioner's testimony that she experienced right shoulder pain within two days of the flu vaccination. Instead, it demonstrates that the pain and discomfort petitioner was experiencing had been ongoing and continued into the following week.

Petitioner also testified that she had called her physician's office to complain about her right arm pain and the swelling. Tr. 62. Petitioner testified that the nurse told her, "it just could be a reaction, so do a hot/cold compress to get the swelling down." *Id.* When petitioner did see Dr. Collier on October 19, 2017, three days prior to the urgent care appointment, petitioner testified that Dr. Collier was focused on her anemia, but that she did show him her right shoulder. Tr. 62. Petitioner's testimony is consistent with the medical record from that date. The medical record provides, "Pt states that she is taking Iron and is getting Vitamin B12 shots here, she has some abnormal lab results and Dr. Collier wanted [patient] to come in and discuss treatment options." Pet. Ex. 3 at 6. The fact that Dr. Collier did not record his examination of petitioner's right arm does not definitely establish that her onset occurred outside the requisite time period. As explained in *Kirby,* medical records are not presumed to be accurate and complete as to all the patient's physical conditions. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1382 (Fed. Cir. 2021). The Federal Circuit explained that "A patient having a heart attack is not likely to mention his runny nose, nor is his physician likely to record it." *Id.* at 1838. Physicians may enter information incorrectly, and "typically record only a fraction of all that occurs." *Id.* at 1378, (citing *Shapiro v. Sec'y of Health & Human Servs.,* 101 Fed. Cl. 532, 538 (2011) (citing *Murphy v. Sec'y of Health & Human Servs.,* 23 Cl. Ct. 726, 733 (1991)). Further, *Kirby* is instructive in this case because it holds that the presumption that medical records are accurate and complete is a faulty one, and silence in a medical record does not establish nonexistence of a problem. *Kirby*, 997 F.3d 1378, 1383. Here petitioner testified that her appointment on October 19, 2017 was focused on her ongoing anemia, because Dr. Collier was concerned about some new abnormal lab results. Tr. 62. Which was consistent with the medical record from that date. Further, petitioner testified that Dr. Collier instructed to her to seek additional treatment if her arm continued to be painful, which is precisely what petitioner did on October 22, 2017, when she went to the urgent care facility.

The urgent care record, which respondent argues put onset at least two weeks after vaccination is given less weight because it contains internal inconsistencies and incorrectly records the date of petitioner's vaccination. *See* Pet. Ex. 3 at 1. First, the record states that petitioner received a flu shot "one week ago," which is inaccurate. Petitioner received her flu vaccination on October 5, 2017, which is approximately two weeks prior to this appointment. Additionally, the record contains multiple internal inconsistencies. The "Intake Comments" and "History of Present Illness" sections are inconsistent with one another as to the "onset" of petitioner's shoulder injury. The "Intake Comment" states that petitioner was complaining of right upper arm pain…area caving in onset this morning," while the "History of Present Illness" section states, "Shoulder pain/injury. Onset 3 to 5 days ago. It occurs constantly." *Id.* Further, the "Review of Systems" section does not reflect that petitioner was experiencing pain in her right arm or that she had a visible "caving" area on her right deltoid in any category, despite petitioner reporting pain on her right shoulder and Physician Assistant Bemo noting that petitioner had a "visible lesion" on her right shoulder. Thus, the urgent care record, is given little weight as to the determination of the onset of petitioner's right shoulder pain and dysfunction.

Further, when petitioner sought medical care for her right shoulder, she consistently related her shoulder pain to the flu vaccination she received on October 5, 2017. When petitioner goes back to Dr. Collier's office on October 24, 2017, the record provides:

> Pt was here on 10/5/2017 for a flu shot and was given Fluzone Quad 0.5 ml dosage IM….given by Jennifer Russell on Right deltoid. She was seen at UCGC today and was told she has "fat wasting" as a result of the flu shot and she needed to be seen here immediately, [patient] states that she went to take a shower, states [her] arm started getting numb, states that sweat was just pouring over here, [patient] states she went to urgent care states they told her "my fat wasting away due to the virus in the flu shot." Pt states her arm is sore and warm to touch, [patient]states she is not able to even sleep on that arm it is so sore.

Pet. Ex. 2 at 3. At petitioner's appointment with orthopedist, Dr. Hardage, petitioner again related the onset of her right shoulder pain to her flu shot she received in October 2017. *See* Pet. Ex. 5 at 1. The record provides, "[Petitioner] states that in October she received a flu vaccination into her right deltoid and over the next couple days she developed swelling and pain, and then noted an indentation in the lateral aspect of her shoulder." *Id.* This record is consistent with petitioner's testimony, where she stated that the next day her right arm was sore and then over the weekend and into the following week, her arm became sorer and felt heavy. *See* Tr. 73.

As such, I find that petitioner's statements and testimony, along with the supporting testimony of petitioner's family and co-workers, along with the medical records, demonstrate that petitioner's right shoulder pain began within 48 hours after receiving the flu vaccination on October 5, 2017.

c. Pain and reduced range of motion confined to the shoulder

There is nothing in the record to suggest that petitioner was suffering pain or seeking treatment for her right shoulder prior to her flu vaccination, nor did respondent raise any argument regarding this criterion. Additionally, petitioner testified that she had reduced range of motion because she "was having a hard time using [her] arm, trying to comb [her] hair, style [her] hair, and put [her] clothes on." Tr. 79-80.

At the hearing petitioner gave detailed testimony about the onset of her pain and limitation of motion as well as the ongoing nature of her symptoms. Tr. 61. She also presented the testimony of four witnesses and provided statements from two others. *See* Tr. 4-48. I found the witnesses to be very credible and consistent in describing the earliest stages of the petitioner's pain and in describing the appearance of her shoulder which became evident shortly after the vaccination. *Id*. Several witnesses including her adult daughters and co-workers described limitations in function that petitioner experienced after the onset of her shoulder injury. *Id*. The petitioner and the witnesses consistently described the onset of her pain and pain complaints and described their observations of her limited function in terms of daily functions like getting dressed, brushing her hair, lifting a baby, sorting mail and carrying boxes at work among other things. *Id*. It was obvious that her supervisor and co-workers regarded her as a hardworking and reliable worker who suffered observable impairments in carrying out the daily functions of her job that she readily did before. *Id*.

As such, petitioner has demonstrated by preponderant evidence that he pain and reduced range of motion was confined to her right shoulder in which her intramuscular flu vaccine was

administered on October 5, 2017, that the pain and dysfunction of her arm was not present before, that it began within a day or two of the vaccination and has limited her function for many months after it began.

d. No other condition or abnormality explains petitioner's symptoms

Respondent's final argument against petitioner's SIRVA claim is that any pain she developed after the flu vaccination on October 5, 2017 is "attributable to her lipodystrophy from B12 injections," and, this condition "explains [her] symptoms following vaccination." Resp. Brief at 23.

Respondent asserted that both medical experts in this case "agree that petitioner developed lipodystrophy in October 2017, from her prior B12 injections, separate and unrelated to the flu vaccination." *Id.* Respondent stated that petitioner did not develop any "abnormal musculoskeletal shoulder findings until February 14, 2018, more than four months after vaccination." *Id.* Additionally, respondent relied on various medical records, all unrelated to the treatment of petitioner's right shoulder, as evidence that petitioner was not experiencing any abnormal right shoulder dysfunction until after she spoke to an attorney. *Id.* at 23-24 (referencing a gastroenterologist visit; an appointment for an endoscopy and colonoscopy; and urgent care visits where petitioner was administered rapid flu tests). Additionally, respondent stated that petitioner's MRI findings are inconsistent with a SIRVA injury and that within one month of seeing an orthopedist, petitioner's musculoskeletal pain resolved. *Id.* at 25. Respondent's last argument, made by Dr. Abrams, was that petitioner's course of symptoms was inconsistent with a SIRVA injury. Tr. 232.

Based on a review of petitioner's medical records and the opinions from both experts in this case, I find that petitioner had presented preponderant evidence that her lipodystrophy was a separate, but concurrent condition, that was not the cause of her right shoulder musculoskeletal pain and decreased mobility.

The parties' experts agreed that petitioner experienced lipoatrophy beginning sometime in October 2017. Resp. Ex. A at 5; Tr. 130. Dr. Abrams stated that, "B12 injections, of which the patient received many to the right shoulder area, are a well-documented cause of lipoatrophy. Examining the medical record, the petitioner was receiving monthly B12 injections since 2013, four years prior to the vaccination in question….In particular, she received B12 injections to the right shoulder nearly every month for the six-month preceding the vaccination in question." Resp. Ex. A at 5; *see also* Pet. Ex. 19 at 23, 26, 28-33. Dr. Bodor agreed with Dr. Abrams, stating "the lipodystrophy likely happened from the multiple B12 injections she had." Tr. 131; Pet. Ex. 27 at 1.

The timing of the onset of petitioner's lipodystrophy would favor the B12 injections as an explanation which more likely would occur over a long period of time. Respondent cites to the *Ho* article, a case report of local sclerodermoid change from multiple B12 injections.[15] Resp. Ex.

[15] Julia Ho, et. al., *Vitamin B12-Associated Localized Scleroderma and Its Treatment*, 30 Dermatol. Surg. 9, 1252-1255 (2004). [Resp. Ex. A Tab 1].

A, Tab 1. Dr. Abrams, referencing the *Ho* article, stated that "importantly, some suggest that a cumulative dose is required to induce these sclerodermoid-type reactions, providing rationale for why the petitioner may not have seen this lesion with her prior B12 injections." Resp. Ex. A; Resp. Ex. A Tab 1 at 3. In this case, petitioner received at least sixty (60) B12 injections in either arm from August 2013 to August 2017, and eight alone were injected into her right arm in 2017. This demonstrates a cumulative dose of B12, which unfortunately led to petitioner suffering from lipodystrophy prior to the flu vaccination on October 5, 2017. Dr. Bodor offered a somewhat speculative theory as to why the indentation presented coincidentally with the pain from the vaccination, but I have not given that serious consideration as the visible indentation characterized as lipodystrophy is not the focus of the petitioner's SIRVA complaint.

At the same time, I do not find Dr. Abram's opinion that the lipoatrophy was the cause of petitioner's acute onset right shoulder pain and dysfunction to be persuasive. The experts essentially agreed that petitioner also suffered a condition known as lipodystrophy which accounted for the visible indentation in her arm. *See* Resp. Ex. A at 5; Pet. Ex. 27 at 3. This local condition in her arm essentially is caused by a loss of fat cells in the subcutaneous tissue. Pet. Ex. 27 at 3. It has been associated with repetitious injections such as B-12 or insulin. Dr. Bodor explained that lipodystrophy is not a disorder affecting muscles, tendon, or bone, and it would be unlikely to cause the deeper pain petitioner described or impairment of motion that was demonstrated during physical examination.

Importantly, Dr. Abram's conceded that "it is certainly possible" that the lipodystrophy does not explain the petitioner's shoulder pain. Resp. Ex. C. at 4. Dr. Abrams also suggested that the B12 injections petitioner received may have been administered into petitioner's subcutaneous tissue, as "lipoatrophy is a pathology of the subcutaneous tissue." Tr. 204. This would support Dr. Bodor's opinion that the lipoatrophy petitioner experienced would be limited to her skin and the subcutaneous fat layer. Finally, petitioner's characterization of the pain as "throbbing" and how she felt the pain "deeper" in her shoulder, makes it more likely that the pain she was experiencing was not associated with the lipoatrophy, which only affected her subcutaneous fat and skin. Tr. 74. Instead, she described musculoskeletal type pain and limitation of motion that is quite consistent with what is often described in SIRVA cases.

Dr. Abrams also opined that petitioner did not experience a SIRVA because "there [was] no evidence of onset of pain within 48 hours after the vaccination in the medical records. Tr. 212; 236-40. However, a delay in seeking treatment for shoulder pain is not an automatic preclusion for finding a Table SIRVA. *See Yost v. Sec'y of Health & Human Servs.,* No. 18-288, 2021 WL 2326403, at *12 (Fed. Cl. Spec. Mstr. May 6, 2021) (finding petitioner's reason for delaying treatment of her shoulder pain to be credible and reasonable); *Drumm v. Sec'y of Health & Human Servs.,* No. 19-276V, 2021 WL 4770124, at *4-5 (Fed. Cl. Spec. Mstr. Spet. 9, 2021) (finding that petitioner's explanation that she anticipated the pain to go away on its own as a reasonable reason to delay treatment). Further, petitioner testified that she had thought the pain she was experiencing after the flu vaccination was "normal," stating, "After I got my regular flu shots, they would always hurt a day or two and then they would just go away. I didn't think nothing of it until it started getting worse." Tr. 73. In SIRVA cases, petitioners often explain that they've delayed treatment thinking that his or her injury would resolve on its own. *See Dhanoa v. Sec'y of Health & Human Servs.,* No. 15-101V, 2017 WL 6276468, at *5 (Fed. Cl.

Spec. Mstr. Apr. 19, 2017) (noting a lack of shoulder complaints at post-vaccination medical appointments because petitioner believed her symptoms represented normal post-vaccination pain).

Petitioner also testified that she told Dr. Collier about her right shoulder pain while she was being treated for anemia on October 17, 2017, but it was not recorded. Tr. 78. As the Federal Circuit discussed in *Kirby,* there is no presumption that medical records are accurate and complete even as to all physical conditions. *Kirby*, 997 F.3d at 1397. It is appropriate to credit the testimony of a petitioner when the testimony does not conflict with the medical records. *Id.* Here, petitioner credibly testified why the record from October 17, 2017 does not contain a reference to her right shoulder pain and her testimony does not conflict with the record. Further, petitioner had multiple witnesses testify that petitioner had told them that she was experiencing right shoulder pain that began within 48 hours after the vaccination. *See* Tr. 24; 61.

Respondent's other argument, that petitioner's symptom and clinical course was inconsistent with a SIRVA is also unpersuasive. Dr. Abrams stated that petitioner's symptom course was inconsistent with a SIRVA because her shoulder symptomatology had a "fluctuating course," which is more "consistent with the high prevalence of shoulder pain in the general population." Resp. Ex. C at 4; Tr. 232. He also argued that her physical exam findings, along with her MRI were inconsistent with most SIRVA cases. Tr. 238.

Petitioner and petitioner's witnesses testified that petitioner's shoulder pain began within forty-eight hours of the vaccination and that she struggled with shoulder mobility issues. For example, petitioner's daughter, Ms. Stephenson testified that petitioner was complaining of "lots of pain" and that "she couldn't do things like she normally could….At the time, she was raising one of my nieces and had a hard time doing her daily activities, like changing diapers, doing dishes, having a hard time getting dressed because of the pain." Tr. 24. During cross-examination, Ms. Stephenson explained that petitioner was having a "hard time lifting her arm because of the pain." Tr. 32. When petitioner was seen by orthopedist, Dr. Hardage on February 14, 2018, petitioner reported that she had "progressively worsening pain with any reaching away from body or overhead." Pet. Ex. 5 at 1. Petitioner also reported muscle weakness and pain lying on her right side. *Id.* Additionally, the physical exam showed petitioner had "positive impingement signs, weakness with external rotation of the shoulder, mild weakness in the supraspinatus," and she had some reduced range of motion on abduction due to pain. *Id.* at 2. Dr. Hardage diagnosed petitioner with a "SIRVA Vaccination Injury," and referred petitioner to physical therapy. *Id.* at 3.

Petitioner's symptom and clinical course is consistent with other SIRVA cases where petitioners have been entitled to compensation. In *Lang*, another SIRVA case, the petitioner sought treatment nearly two and half months after receiving the shot, but still complained of pain in the shoulder where the injection was given. *Lang v. Sec'y of Health & Human Servs.* No. 17-995V, 2020 WL 7873272, at *2. Additionally, the petitioner had positive impingement signs, demonstrated decreased range of motion in the affected shoulder, and mild weakness in flexion and external rotation. *Id.* The petitioner in *Lang* was also diagnosed with a SIRVA and recommended that she participate in physical therapy. *Id.*

The findings on petitioner's MRI are not indicative of "whether any other condition could explain petitioner's symptoms," but instead are consistent with the SIRVA literature filed in this case and also which respondent relied when adding SIRVA to the Vaccine Injury Table. The *Atanasoff* article, which respondent relied upon for creating the QAI for SRIVA explains that:

> In general, chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions including, impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis, and adhesive capsulitis. In many cases these conditions may cause no symptoms until provoked by trauma or other events. Reilly et al reviewed a series of shoulder ultrasounds and MRI studies obtained in asymptomatic persons past middle age and found partial or complete rotator cuff tears in 39% of these individuals. Therefore, some of the MRI findings in our case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation.

Pet. Ex. 26 at 3; *see also* Proposed Rulemaking, 2015 WL 4538923, at *45136.

Here, petitioner's MRI findings may have been age-expected as Dr. Abrams opined, but became symptomatic after the vaccination at issue, which is consistent with the *Atanasoff* and *Barnes* articles. *See* Pet. Ex. 26; Resp. Ex. A, Tab 10. These findings are also consistent with other SIRVA cases in the program. In *Lang,* Special Master Horner observed that a follow-up study of SIRVA cases by the Department of Health and Human Services found that "among the compensated claims examined, 16.2% had evidence on MRI of acromioclavicular arthritis, a further 16.2% had labral tears, and over 40% had either complete or partial rotator cuff tears." *Lang,* at * 13. Thus, evidence of rotator cuff tears, as existed on petitioner's MRI, along with likely other degenerative changes, does not *per se* preclude a finding that a Table SIRVA exits. *See Grossman v. Sec'y of Health & Human Servs.,* No. 18-13V, 2022 WL 779666 (citing *Lang,* at *18).

Further, Dr. Abrams' opinion that petitioner's right shoulder pain was more likely caused by age-related changes to her shoulder structure contradicts the opinion of petitioner's treating orthopedist, Dr. Hardage. Dr. Hardage assessed petitioner on February 14, 2018, reviewing petitioner's medical history, including the onset of her pain occurring and continuing for four months after she received the flu vaccine on October 5, 2017, diagnosed petitioner with a SIRVA. Pet. Ex. 5 at 2. Petitioner's treating physician, Dr. Hardage was in the best position to make judgments as to the clinical significance of her signs and symptoms as he heard her history and performed a physical examination while the petitioner was symptomatic. *See Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1327, 1326 (Fed. Cir. 2006) ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show [s] that the vaccination was the reason for the injury'").

Finally, at the conclusion of testimony, noting that Dr. Abrams had been present to hear all of the witnesses, the Court asked Dr. Abrams whether he thought that petitioner's injury "sounded more like a SIRVA injury," after hearing the testimony by the petitioner and her lay

witnesses. He answered, "Based on what they said, yes." Tr. 239. As I have concluded that the testimony of the witnesses and the petitioner was credible I have also come to that conclusion.

e. Factor unrelated

Pursuant to the Vaccine Act, once petitioner has met her *prima facie* burden of demonstrating a Table Injury, respondent may still prove the condition is "due to factors unrelated to the administration of the vaccine described in the petition." § 300aa-13(a)(1)(B). To the extent that respondent has contended that the B-12 shots and petitioner's lipodystrophy was a factor unrelated I have thoroughly addressed that issue above and find that her pain and dysfunction were caused by the vaccination and not the B-12 injections.

V. Conclusion

For all the reasons discussed above, after weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a Table SIRVA Injury as a result of her October 5, 2017, flu vaccination as she alleged. She is entitled to compensation. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master